



Dkt.1567/65558/JPW/M

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ilan Sela and Sylvia Zeitoune-Simovich

Serial No.: 09/889,821

Int'l Appln. No.: PCT/IL00/00029

Filed : July 18, 2001

Int' Filing Date: January 16, 2000

For : AN EXPRESSION SILENCING SYSTEM AND DIFFERENT USE
THEREOF

1185 Avenue of the Americas
New York, New York 10036
March 5, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

**COMMUNICATION FORWARDING A VERIFIED STATEMENT
(DECLARATION) CLAIMING SMALL ENTITY STATUS UNDER 37 C.F.R.
§1.9 (f) AND §1.27(c) AND INFORMATION DISCLOSURE STATEMENT**

This Communication is submitted in order to establish small entity status under 37 C.F.R. §1.9(f) and §1.27(c) in connection with the above-identified application. Applicants maintain that small entity status was applicable at the time of filing and that such status still applies. In support, applicants attach hereto a Verified Statement (Declaration) Claiming Small Entity Status Under 37 C.F.R. §1.27(c) (Small Business Concern) for Yisum Research Development Company of the Hebrew University of Jerusalem (**Exhibit A**). The Statement is signed by the authorized official of the entity that has rights in the subject application, namely Yisum Research Development Company of the Hebrew University of Jerusalem.

In the event that the United States Patent and Trademark Office charged any fees in addition to those required for a small entity, applicants hereby request a refund for any such fees. This refund should be credited to Deposit Account No. 03-3125 under Docket No. 65558.

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INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references which are listed on the PTO-1449 form attached hereto as **Exhibit B**. Copies of these references are attached hereto as **Exhibits 1-49**, respectively.

1. U.S. Patent No. 5,545,817, issued August 13, 1996 to McBride et al. (**Exhibit 1**);
2. U.S. Patent No. 5,659,124, issued August 19, 1997 to Crossland et al. (**Exhibit 2**);
3. PCT International Application No. PCT/GB98/00442, filed February 12, 1998, International Publication No. WO 98/36083, published August 20, 1998 on behalf of Plant Bioscience Limited (**Exhibit 3**);
4. PCT International Application No. PCT/AU98/00078, filed February 11, 1998, International Publication No. WO 98/34951, published August 13, 1998 on behalf of Amrad Operations Pty. Ltd. (**Exhibit 4**);
5. PCT International Application No. PCT/GB98/01450, filed May 20, 1998, International Publication No. WO 98/53083, published November 26, 1998 on behalf of Zeneca Limited (**Exhibit 5**);
6. PCT International Application No. PCT/GB97/00178, filed January 21, 1997, International Publication No. WO 97/27295, published July 31, 1997 on behalf of Horticulture Research International (**Exhibit 6**);

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7. An, G. (1987) "Binary Ti Vectors for Plant Transformation and Promoter Analysis" Methods Enzymol 153: 292-305 (Exhibit 7);
8. Baulcombe, D.C. et al. (1996) "Ectopic Pairing of Homologous DNA and Post-Transcriptional Gene Silencing in Transgenic Plants" Curr. Opin. Biotechnol. 7:173-180 (Exhibit 8);
9. Boerjan, W. et al. (1994) "Distinct Phenotypes Generated by Overexpression and Suppression of S-Adenosyl-L-Methionine Synthetase Reveal Developmental Patterns of Gene Silencing in Tobacco" Plant Cell 6:1401-1414 (Exhibit 9);
10. Caviedes, M.A. et al. (1994) "T7 RNA Polymerase is Expressed in Plants in a Nicked But Active Form" The 4th Intl. Congress of Plant Mol. Biol. Abstract #479 (Exhibit 10);
11. Chamberlin, M. et al. (1982) "Bacteriophage DNA-Dependent RNA Polymerases" in 15 The Enzymes 87-108 (Boyer P.D. ed., Academic Press) (Exhibit 11);
12. Cox, K.H. et al. "Analysis of Plant Gene Expression" in Plant Molecular Biology, A Practical Approach 1-35 (Shaw, C.H. ed., IRL Press) (Exhibit 12);
13. De Carvalho-Niebal, F. et al. (1995) "Post-Transcriptional Cosuppression of β -1,3-Glucanase Genes Does Not Affect Accumulation of Transgene Nuclear mRNA" Plant Cell 7:347-358 (Exhibit 13);
14. Depicker, A. et al. (1997) "Post-transcriptional Gene Silencing in Plants" Curr. Opin. Cell Biol. 9:373-382 (Exhibit 14);

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15. Dunn, J.J. et al. (1983) "Complete Nucleotide Sequence of Bacteriophage T7 DNA and the Locations of T7 Genetic Elements" J. Mol. Biol. **166**:477-535 (Exhibit 15);
16. Dunn, J.J. et al. (1988) "Targeting Bacteriophage T7 RNA Polymerase to the Mammalian Cell Nucleus" Gene **68**:259-266 (Exhibit 16);
17. Flavell, R.B. et al. (1994) "Inactivation of Gene Expression in Plants as a Consequence of Specific Sequence Duplication" Proc. Natl. Acad. Sci. USA **91**:3490-3496 (Exhibit 17);
18. Fuerst, T. R. et al. (1987) "Use of a Hybrid Vaccinia Virus-T7 RNA Polymerase System for Expression of Target Genes" Mol. Cell. Biol. **7**:2538-2544 (Exhibit 18);
19. Fuerst, T.R. et al. (1986) "Eukaryotic Transient-Expression System Based on Recombinant Vaccinia Virus That Synthesizes Bacteriophage T7 RNA Polymerase" Proc. Natl. Acad. Sci. USA **83**:8122-8126 (Exhibit 19);
20. Gallie, D.R. et al. (1987) "The 5'-leader Sequence of Tobacco Mosaic Virus RNA Enhances the Expression of Foreign Gene Transcripts *In Vitro* and *In Vivo*" Nucleic Acids Research **15**:3257-3273 (Exhibit 20);
21. Goodwin, J. et al. (1996) "Genetic and Biochemical Dissection of Transgenic RNA-Mediated Virus Resistance" Plant Cell **8**:95-105 (Exhibit 21);
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- 23.-----Lassner, M.W. et al. (1991) "Targeting of T7 RNA Polymerase to Tobacco Nuclei Mediated by an SV40 Nuclear Location Signal" Plant Mol. Biol. 17:229-234 (Exhibit 23);
24. Lin, C.H. et al. (1997) "Optimization of Electroporation Conditions for Expression of GUS Activity in Electroporated Protoplasts and Intact Plant Cells" Plant Physiol. Biochem. 35:959-968 (Exhibit 24);
25. Lieber, A. et al. (1989) "High Level Gene Expression in Mammalian Cells by a Nuclear T7-Phage RNA Polymerase" Nucleic Acids Research 17:8485-8493 (Exhibit 25);
26. Lindbo, J.A. et al. (1993) "Induction of a Highly Specific Antiviral State in Transgenic Plants: Implications for Regulation of Gene Expression and Virus Resistance" Plant Cell 5:1749-1759 (Exhibit 26);
27. Matzke, M.A. et al. (1994) "Inactivation of Repeated Genes-DNA-DNA Interaction?" in Homologous Recombination and Gene Silencing in Plants 271-307 (J. Paszkowski ed., Kluwer Academic Publishers) (Exhibit 27);
28. Matzke, M.A. (1990) "Gene Interactions and Epigenetic Variation in Transgenic Plants" Dev. Genet. 11:214-223 (Exhibit 28);
29. Matzke, M.A. et al. (1989) "Reversible Methylation and Inactivation of Marker Genes in Sequentially Transformed Tobacco Plants" EMBO J. 8:643:649 (Exhibit 29);
30. Matzke, M.A. et al. (1993) "A Variety of Epistatic Interactions Can Occur Between Partially Homologous Transgene Loci Brought Together by Sexual Crossing" Mol.

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Gen. Genet. 236:379-386 (Exhibit 30);

31. McBride, K.E. et al. (1994) "Controlled Expression of Plastid Transgenes in Plants Based on a Nuclear DNA-encoded and Plastid-targeted T7 RNA Polymerase" Proc. Natl. Acad. Sci. USA 91:7301-7305 (Exhibit 31);
32. Metzlauff, M. et al. (1997) "RNA-Medicated RNA Degradation and Chalcone Synthase a Silencing in Petunia" Cell 88:845-854 (Exhibit 32);
33. Meyer, P. et al. (1996) "Homology-Dependent Gene Silencing In Plants" Annu. Rev. Plant Physiol. Plant Mol. Biol. 47:23-48 (Exhibit 33);
34. Moffatt, B.A. et al. (1984) "Nucleotide Sequence of the Gene for Bacteriophage T7 RNA Polymerase" J. Mol. Biol. 173:265-269 (Exhibit 34);
35. Montgomery, M.K. et al. (1998) "Doubled-stranded RNA as a Mediator in Sequence-Specific Genetic Silencing and Co-suppression" Trends in Genetics 14:255-258 (Exhibit 35);
36. Moss, B. et al. (1990) "New Mammalian Expression Vectors" Nature 348:91-92 (Exhibit 36);
37. Mueller, E. et al. (1995) "Homology-dependent Resistance: Transgenic Virus Resistance in Plants Related to Homology-dependent Gene Silencing" Plant J. 7:1001-1013 (Exhibit 37);
38. Murashige, T. et al. (1962) "A Revised Medium for Rapid Growth and Bio Assays with Tobacco Tissue Cultures" Physiol. Plant. 15:473-497 (Exhibit 38);

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39. Napoli, C. et al. (1990) "Introduction of a Chimeric Chalcone Synthase Gene into Petunia Results in Reversible Co-Suppression of Homologous Genes *in trans*" Plant Cell **2**:279-289 (Exhibit 39);
40. Smith, C.J.S. et al. (1990) "Expression of a Truncated Tomato Polygalacturonase Gene Inhibits Expression of the Endogenous Gene in Transgenic Plants" Mol. Gen. Genet. **224**:477-481 (Exhibit 40);
41. Stam, M. et al. (1997) "The Silence of Genes in Transgenic Plants" Ann. Bot. **79**:3-12 (Exhibit 41);
42. Studier, F.W. et al. (1986) "Use of Bacteriophage T7 RNA Polymerase to Direct Selective High-level Expression of Cloned Genes" J. Mol. Biol. **189**:113-130 (Exhibit 42);
43. Tabor, S. et al. (1985) "A Bacteriophage T7 RNA Polymerase/Promoter System for Controlled Exclusive Expression of Specific Genes" Proc. Natl. Acad. Sci. USA **82**:1074-1078 (Exhibit 43);
44. Tanzer, M.M. et al. (1997) "Characterization of Post-Transcriptionally Suppressed Transgene Expression That Confers Resistance to Tobacco Etch Virus Infection in Tobacco" Plant Cell **9**:1411-1423 (Exhibit 44);
45. Tuttle, A. et al. (1994) "Expression of T7 Transcripts in Plant Cells By Bacteriophage T7 RNA Polymerase" The 4th Intl. Congress of Plant Mol. Biol. Abstract#478 (Exhibit 45);
46. Van Blokland R. et al. (1994) "Transgene-mediated Suppression of Chalcone Synthase Expression in *Petunia hybrida* Results from an Increase in RNA Turnover" Plant J.

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6:861-877 (**Exhibit 46**);

47. Vardi, E. et al. (1993) "Plants Transformed with a Cistron of a Potato Virus Y Protease (Nia) are Resistant to Virus Infection" Proc. Natl. Acad. Sci. USA 90:7513-7517 (**Exhibit 47**);
48. Weschke, W. et al. (1994) "T7 RNA Polymerase Mediated Expression in Transgenic *N. Tabaccum* Plants" The 4th Intl. Congress of Plant Mol. Biol. Abstract #480 (**Exhibit 48**);
and
49. Zeitoune, S. et al. (1999) "T7 RNA Polymerase Drives Transcription of a Reporter Gene from T7 Promoter, But Engenders Post-Transcriptional Silencing of Expression" Plant Science 141:59-65 (**Exhibit 49**).

The subject application is a national stage application under 35 U.S.C. §371 of PCT International Application No. PCT/IL00/00029, filed January 16, 2000. An International Search Report was issued on June 20, 2000 in connection with PCT International Application No. PCT/IL00/00029. A copy of the Search Report is attached hereto as **Exhibit C**. Above listed references 3, 4, 5, 6, 23, 35 and 49 were cited in the Search Report. In addition, an International Preliminary Examination Report was issued on June 1, 2001 in connection with PCT International Application No. PCT/IL00/00029. A copy of the International Preliminary Examination Report is attached hereto as **Exhibit D**. Above listed references 3, 23 and 35 were cited in the Preliminary Search Report.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number

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provided below.

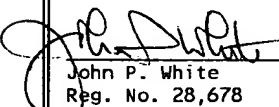
No fee is deemed necessary in connection with the filing of this Communication and Information Disclosure Statement. If any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Attorney for Applicants
Cooper & Dunham, LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.



John P. White
Reg. No. 28,678

3/5/02
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Ilan Sela and Sylvia Zeitoune-Simovich

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U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	US 5 5 4 5 8 1 7	8/13/96	McBride et al. (Exhibit 1);			
	US 5 6 5 9 1 2 4	8/19/97	Crossland et al. (Exhibit 2);			

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
	WO 9 8 3 6 0 8 3	8/20/98 (Exhibit 3);					
	WO 9 8 3 4 9 5 1	8/13/98 (Exhibit 4);					
	WO 9 8 5 3 0 8 3	11/26/98 (Exhibit 5);					
	WO 9 7 2 7 2 9 5	7/31/97 (Exhibit 6);					

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	An, G. (1987) "Binary Ti Vectors for Plant Transformation and Promoter Analysis" <u>Methods Enzymol</u> 153: 292-305 (Exhibit 7);
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Zeitoune-Simovich
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Exhibit B

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Chamberlin, M. et al. (1982) "Bacteriophage DNA-Dependent RNA Polymerases" in 15 <u>The Enzymes</u> 87-108 (Boyer P.D. ed., Academic Press) (Exhibit 11);
	Cox, K.H. et al. "Analysis of Plant Gene Expression" in <u>Plant Molecular Biology, A Practical Approach</u> 1-35 (Shaw, C.H. ed., IRL Press) (Exhibit 12);
	De Carvalho-Niebal, F. et al. (1995) "Post-Transcriptional Cosuppression of β -1,3-Glucanase Genes Does Not Affect Accumulation of Transgene Nuclear mRNA" <u>Plant Cell</u> 7:347-358 (Exhibit 13);
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		Dunn, J.J. et al. (1983) "Complete Nucleotide Sequence of Bacteriophage T7 DNA and the Locations of T7 Genetic Elements" <u>J. Mol. Biol.</u> 166 :477-535 (Exhibit 15);
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		Mueller, E. et al. (1995) "Homology-dependent Resistance: Transgenic Virus Resistance in Plants Related to Homology-dependent Gene Silencing" <u>Plant J.</u> 7 :1001-1013 (Exhibit 37) ;
		Murashige, T. et al. (1962) "A Revised Medium for Rapid Growth and Bio Assays with Tobacco Tissue Cultures" <u>Physiol. Plant.</u> 15 :473-497 (Exhibit 38) ;
		Napoli, C. et al. (1990) "Introduction of a Chimeric Chalcone Synthase Gene into Petunia Results in Reversible Co-Suppression of Homologous Genes <i>in trans</i> " <u>Plant Cell</u> 2 :279-289 (Exhibit 39) ;

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		Stam, M. et al. (1997) "The Silence of Genes in Transgenic Plants" <u>Ann. Bot.</u> 79 :3-12 (Exhibit 41) ;
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Applicants

Ilan Sela and Sylvia Zeitoune-Simovich

Filing Date

July 18, 2001

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FOREIGN PATENT DOCUMENTS

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		Document Number							Date	Country	Class	Subclass	Translation		
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Tanzer, M.M. et al. (1997) "Characterization of Post-Transcriptionally Suppressed Transgene Expression That Confers Resistance to Tobacco Etch Virus Infection in Tobacco" <u>Plant Cell</u> 9 :1411-1423 (Exhibit 44);
		Tuttle, A. et al. (1994) "Expression of T7 Transcripts in Plant Cells By Bacteriophage T7 RNA Polymerase" <u>The 4th Intl. Congress of Plant Mol. Biol.</u> Abstract#478 (Exhibit 45);
		Van Blokland R. et al. (1994) "Transgene-mediated Suppression of Chalcone Synthase Expression in <i>Petunia hybrida</i> Results from an Increase in RNA Turnover" <u>Plant J.</u> 6 :861-877 (Exhibit 46);
		Vardi, E. et al. (1993) "Plants Transformed with a Cistron of a Potato Virus Y Protease (Nla) are Resistant to Virus Infection" <u>Proc. Natl. Acad. Sci. USA</u> 90 :7513-7517 (Exhibit 47);

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**U.S. Department of Commerce
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Atty. Docket No.

1567/65558/JPW/MVM

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		Weschke, W. et al. (1994) "T7 RNA Polymerase Mediated Expression in Transgenic <i>N. Tabaccum</i> Plants" <u>The 4th Intl. Congress of Plant Mol. Biol.</u> Abstract #480 (Exhibit 48); and
		Zeitoune, S. et al. (1999) "T7 RNA Polymerase Drives Transcription of a Reporter Gene from T7 Promoter, But Engenders Post-Transcriptional Silencing of Expression " <u>Plant Science</u> 141 :59-65 (Exhibit 49).

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